General

Guideline Title

Bi-level positive airway pressure (BPAP) devices.

Bibliographic Source(s)

AIM Specialty Health. Bi-level positive airway pressure (BPAP) devices. Chicago (IL): AIM Specialty Health; 2014 May 20. 5 p. [10 references]

Guideline Status

This is the current release of the guideline.

Recommendations

Major Recommendations

Bi-Level Positive Airway Pressure (BPAP) (without back-up rate feature)

- Appropriate for patients with obstructive sleep apnea (OSA) who have failed continuous positive airway pressure (CPAP)/auto-titrating positive airway pressure (APAP) or require supplemental ventilatory support due to a hypoventilation syndrome

BPAP (with back-up rate feature)

- Appropriate for patients with established central sleep apnea (CSA) diagnosed by an in-lab sleep study demonstrating all of the following:
  a. OSA has been excluded or treated
  b. Oxygen saturation level is 88% or less for at least five (5) continuous minutes while the patient breathes his/her usual fraction of inspired oxygen (FiO_2) OR the patient demonstrates Cheyne-Stokes respiration for five (5) continuous minutes with oxygen saturation falling to 88% or less at least once during that 5 minute interval
  c. A titration study (split-night or whole-night) has demonstrated significant improvement of sleep-related hypoventilation adjusted to the settings that will be prescribed for home use (while breathing the individual's usual FiO_2)

BPAP (with or without back-up rate feature)

- Appropriate in the management of patients with severe chronic obstructive pulmonary disease (COPD) demonstrating either of the following:
  a. Partial pressure of arterial carbon dioxide ($PaCO_2$) measured by arterial blood gas drawn while the patient is awake and breathing his/her usual FiO_2 is 45 mmHg or greater; OR

b. Sleep oximetry demonstrates oxygen saturation of 88% or less for at least five continuous minutes while the patient breathes oxygen at 2 L per minute or his/her usual FiO_2 (whichever is higher)

BPAP (with or without back-up rate feature)

- Appropriate in the management of patients with certain restrictive thoracic disorders when both a and b below are true:
  a. The patient has an established diagnosis of a progressive neuromuscular disease (e.g., amyotrophic lateral sclerosis [ALS]) OR a severe thoracic cage abnormality; AND
  b. One of the following statements is true:
     - $PaCO_2$ measured by arterial blood gas drawn while the patient is awake and breathing his/her usual FiO_2 is 45 mmHg or greater.
     - Sleep oximetry demonstrates oxygen saturation of 88% or less for at least five continuous minutes while the patient breathes his/her usual FiO_2
     - Maximal inspiratory pressure is less than 60 cm H_2O or forced vital capacity is less than 50% of predicted (applies to patients with progressive neuromuscular disease only)

Ongoing Treatment with BPAP

Ongoing treatment is indicated for patients who demonstrate compliance with therapy. Demonstration of compliance is required every 90 days for the first year of treatment and annually thereafter. Compliance is defined as:

1. Use of the BPAP device for greater than or equal to four (4) hours per night on 70% of nights during a consecutive thirty (30) day period within the preceding 90 days; OR
2. There is clinical evidence submitted by the treating provider that demonstrates continued clinical benefit from use of the positive airway pressure device.

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

- Sleep disorders, including:
  - Obstructive sleep apnea (OSA)
  - Central sleep apnea (CSA)
  - Mixed sleep disorders
- Chronic obstructive pulmonary disease (COPD)
- Restrictive thoracic disorders

Guideline Category

Assessment of Therapeutic Effectiveness

Management

Treatment

Clinical Specialty

Family Practice

Internal Medicine

Neurology

Pulmonary Medicine

Sleep Medicine

Intended Users

Advanced Practice Nurses

Allied Health Personnel

Health Plans

Managed Care Organizations

Nurses

Physician Assistants

Physicians

Respiratory Care Practitioners

Guideline Objective(s)

To provide appropriate indications for bi-level positive airway pressure (BPAP) devices

Target Population

Patients with established sleep disorders (obstructive sleep apnea [OSA], central sleep apnea [CSA], or mixed sleep disorders), severe chronic obstructive pulmonary disease (COPD), and certain restrictive thoracic disorders requiring initial or ongoing therapy with bi-level positive airway pressure (BPAP) systems and associated supplies

Interventions and Practices Considered

Bi-level positive airway pressure (BPAP)

Major Outcomes Considered

- Reduction of apnea-hypopnea index (AHI)
- Refreshing night-time sleep
- Compliance with therapy

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

Review of AIM Guideline References

The first screening process identified 52 AIM Specialty Health (AIM) guideline references relevant to the guideline. A full-text review retained 38 references and 1 article was added from reference list.

Guidelines Search

A manual search of the American Academy of Sleep Medicine (AASM) and American Thoracic Society (ATS) Web sites was conducted on February 3, 2014 yielding 9 systematic reviews and 17 guidelines. A National Guideline Clearinghouse search using the keywords "sleep apnea", "polysomnography", "sleep apnoea", "narcolepsy", and "positive airway pressure" was conducted on the same day, yielding 108 results. These searches resulted in 3 guidelines for full-text review. Two of these guidelines were added to the evidence tables.

Scientific Literature Update Search

A manual search of the Institute for Clinical Systems Improvement (ICSI), Blue Cross Blue Shield Health Technology Assessment (BCBS HTA), Oregon Health Evidence Review Commission, Washington HTA Program, National Health Service (NHS) HTA Programme and of the Institute for Clinical and Economic Review (ICER), the Agency for Healthcare Research and Quality (AHRQ), the Canadian Agency for Drugs and Technologies in Health (CADTH), California committee, and the Centers for Medicare and Medicaid Services (CMS) for grey literature on February 4, 2014 gave 1 result and 5 reports, respectively. Two reports had full-text review and were added to the evidence tables. A PubMed/MEDLINE update search on the same day for literature published from January 2012 to February 2014, using keywords and index terms for polysomnography, home sleep testing, positive airway pressure treatment, oral appliances, and narcolepsy yielded 767 results. Fifty-four had abstract review and 2 articles were added through ongoing surveillance. Thirty-one of these articles had full-text review and 19 of these were added to the evidence tables.

Research Process

The research and development process is primarily conducted by the lead physician author with staff support, including medical librarians, and is overseen by the AIM members of the Clinical Guidelines Committee (CGC). The resources considered during AIM Guidelines development can include but are not limited to:

- Professional Society Guidelines
- Professional Society Appropriateness Criteria
- Agency for Healthcare Research and Quality (AHRQ) Comparative Effectiveness Guidance
- The Centers for Medicare and Medicaid Services (CMS)
- Initiatives sponsored by Specialty Licensing Boards

Additional web-based searches for evidence-based clinical guidelines and appropriate use criteria may also be performed using the National Guideline Clearinghouse website. Searches of the primary literature for an AIM Guideline under review are also conducted using standard databases and clinical knowledge resources. Relevant evidence-based literature or information may be brought to AIM's attention at any time by providers, AIM's physician reviewers, committee members, or other interested parties. This additional information may warrant off-cycle review and modification to include clinically-important recommendations, in addition to the usual process as determined by the Chair of the CGC.

A database is used to track the various sources of information referenced. A digital copy of each source document, including primary literature, is stored. If the content license prohibits storing a digital copy, a print copy is stored. Quality data on actual case review by AIM's physician reviewers using the guidelines under consideration shall also be made available during the guideline review process.

Number of Source Documents

Sixty-three references were in the evidence tables reviewed by expert panelists. No guideline recommendation changes were made. For this guideline, 3 references were retained, 17 were removed, and 7 added during review.

Methods Used to Assess the Quality and Strength of the Evidence

Expert Consensus

Rating Scheme for the Strength of the Evidence

Not applicable

Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

Evidence tables were organized around key clinical questions, some applicable to multiple guidelines.

Key Clinical Questions

1. In adults and children in whom positive airway pressure (PAP) has been recommended as treatment for obstructive sleep apnea (OSA), what is the compliance rate?
2. What are the indications for positive pressure therapy in diagnoses other than sleep-disordered breathing?

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

Guideline Development and Review Process

Review Process

When a new Guideline(s) is considered, the Chair of the Clinical Guidelines Committee (CGC) may choose to form a Specialty Panel to assist with the drafting and review of the Guideline. Similarly, the assigned AIM Medical Director may use a Specialty Panel to review and comment on proposed revisions to existing Guidelines.

In order for a new or revised Guideline to be approved for use by AIM, it must be reviewed by the Internal Panel of AIM physician reviewers. The Internal Panel considers supporting evidence as well as usability and validity within the education and adjudication process. The Internal Panel votes to forward recommendations to the Independent Physician Panel.

The Independent Physician Panel considers supporting evidence and the potential impact of draft AIM Guidelines on clinical outcomes and practice. The external panel votes to forward recommendations onto the CGC.

An AIM Medical Director is assigned to each program or solution for purposes of the guideline development and review process. These AIM Medical Directors are responsible for drafting new Guidelines as necessary and ensuring that every Guideline and the procedures for applying it, is reviewed and assessed for continued validity at least once annually. The assigned AIM Medical Directors are responsible for monitoring the clinical and regulatory environment with the support of AIM medical librarians to determine when Guideline revisions are necessary, based on new, potentially-relevant evidence and other factors. The assigned AIM Medical Directors are responsible for supporting the Vice President, Clinical Operations in facilitating education and training for the staff regarding the Guidelines.

Committee and Panel Operational Process

Review requires that the Guideline and any supporting materials be provided to members who are given sufficient time for review. The body then meets (either in person or telephonically) to discuss the proposed changes or enhancements. Approval of a Guideline is demonstrated by a vote of at least a majority of the members of that body who are present at the meeting (but in no event fewer than three [3] affirmative votes). If approval

is received, then the Guideline can proceed to the next stage of the process. If committee approval is not received at any stage of the process, then the assigned AIM Medical Director shall be responsible for addressing committee member concerns and resubmitting the Guideline for committee review.

Minutes of all meetings are maintained as well as documentation of all proposed, approved and tabled Guidelines and changes to Guidelines. All input received during any level of review is recorded and noted in any subsequent review. Input received after approval of a Guideline is presented at the next regularly scheduled CGC meeting.

The AIM Quality Improvement Committee (QIC) reviews and accepts the Guidelines.

Ultimate responsibility and accountability for the development, review and updating of AIM's Guidelines are delegated to the CGC. No new or revised Guideline can be implemented without CGC approval.

Rating Scheme for the Strength of the Recommendations

Not applicable

Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

Method of Guideline Validation

External Peer Review

Internal Peer Review

Description of Method of Guideline Validation

The Clinical Guidelines Committee (CGC) considers medical director feedback and Internal and External Panel recommendations. Data from guidelines use in appropriateness reviews, provider comments, and other feedback are also used in developing recommendation revisions. The CGC is the final and ultimate approving body.

The AIM Quality Improvement Committee (QIC) reviews and accepts the Guidelines.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of evidence supporting the recommendations is not specifically stated.

The recommendations were based on a review of published literature. When evidence was unavailable, limited, unclear, or not directly generalizable to the patient populations under consideration, expert consensus was used to develop recommendations.

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Appropriate use of bi-level positive airway pressure (BPAP) devices for treatment of sleep disorders

Potential Harms

Not stated

Qualifying Statements

Qualifying Statements

- AIM Specialty Health (AIM) has developed proprietary diagnostic and treatment management clinical guidelines (together with any updates, referred to collectively as the "Guidelines"). The Guidelines are designed to evaluate and direct the appropriate management of sleep diagnostic testing and treatment scenarios. They are based on data from the peer-reviewed scientific literature, from criteria developed by specialty societies and from guidelines adopted by other health care organizations. Access to these guidelines is being provided for informational purposes only. AIM is under no obligation to update its Guidelines. Therefore, these Guidelines may be out of date.
- The Guidelines do not constitute medical advice and/or medical care, and do not guarantee results or outcomes. The Guidelines are not a substitute for the experience and judgment of a physician or other health care professionals. Any clinician seeking to apply or consult the Guidelines is expected to use independent medical judgment in the context of individual clinical circumstances to determine any patient's care or treatment. The Guidelines do not address coverage, benefit or other plan specific issues.
- The Guidelines are provided "as is" without warranty of any kind, either expressed or implied. AIM disclaims all responsibility for any consequences or liability attributable or related to any use, non-use or interpretation of information contained in the Guidelines.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

Living with Illness

IOM Domain

Effectiveness

Patient-centeredness

Identifying Information and Availability

Bibliographic Source(s)

AIM Specialty Health. Bi-level positive airway pressure (BPAP) devices. Chicago (IL): AIM Specialty Health; 2014 May 20. 5 p. [10

references]

Adaptation

Not applicable: The guideline is not adapted from another source.

Date Released

2014 May 20

Guideline Developer(s)

AIM Specialty Health - Professional Association

Source(s) of Funding

AIM Specialty Health

Guideline Committee

Clinical Guidelines Committee (CGC)

Composition of Group That Authored the Guideline

Board certified physicians, including three board-certified sleep medicine specialists

Financial Disclosures/Conflicts of Interest

All members of any body are required to report and discuss any potential conflicts of interest. In the event that a member discloses a conflict of interest that may influence the Guideline development process or specific recommendations, the member must not participate in the vote specific to the relevant recommendation. Ongoing review and management of conflict of interest is the responsibility of the Clinical Guidelines Committee (CGC).

Guideline Status

This is the current release of the guideline.

Guideline Availability

Electronic copies: Available by request. Please contact AIM Specialty Health at NGC-request@aimspecialtyhealth.com.

Availability of Companion Documents

None available

Patient Resources

None available

NGC Status

This NGC summary was completed by ECRI Institute on September 25, 2014. The information was verified by the guideline developer on October 23, 2014.

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